

IN THE CLAIMS

1. (original): An oral pharmaceutical dosage form comprising pharmacologically effective amounts of an acid-susceptible proton pump inhibitor or a salt thereof and an H₂ receptor antagonist or a salt thereof, and at least one pharmaceutically acceptable excipient(s) which results in a delayed release and/or extended release of the acid-susceptible proton pump inhibitor or the salt thereof, and said H₂ receptor antagonist or the salt thereof is included in such a way that it is rapidly released from said dosage form.
2. (original): The dosage form of claim 1, wherein the acid-susceptible proton pump inhibitor is selected from lansoprazole, omeprazole, pantoprazole, rabeprazole, pariprazole, leminoprazole, their pharmaceutically acceptable salts, enantiomers and salts of enantiomers.
3. (previously presented): The dosage form of claim 1, comprising from 1 mg to 100 mg of the acid-susceptible proton pump inhibitor or a salt thereof per single dose.
4. (original): The dosage form of claim 1, wherein the H₂ receptor antagonist is selected from cimetidine, ranitidine, nizatidine and famotidine, their pharmaceutically acceptable salts, isomers and salts of isomers.
5. (original): The dosage form of claim 4, comprising from 1 mg to 800 mg of H₂ receptor antagonist or salt thereof.
6. (previously presented): The dosage form of claim 1, wherein the excipient(s) exerts the release controlling activity in the form of a membrane applied onto a core comprising the acid-susceptible proton pump inhibitor or a salt thereof, or in the form of a matrix system where the acid-susceptible proton pump inhibitor or a salt thereof is incorporated into the excipient(s).
7. (previously presented): The dosage form of claim 1, wherein the H₂ receptor antagonist or a salt thereof forms an outer layer applied onto a core comprising the acid-susceptible proton pump inhibitor or a salt thereof and excipients, wherein the core forms a matrix or membrane system, capable of delayed and/or extended release of the acid-susceptible proton pump inhibitor or a salt thereof.

8. (previously presented): The dosage form of claim 1, wherein the excipient(s) used to form the membrane or matrix are inert or lipid.
9. (original): The dosage form of claim 8, wherein the inert excipient(s) are non-polymeric-or polymeric materials such as calcium phosphate, ethyl cellulose, methacrylate copolymer, polyamide, polyethylene, polyvinyl alcohol or polyvinyl acetate.
10. (original): The dosage form of claim 8, wherein the lipid excipient(s) are non-polymeric-or polymeric materials such as carnauba wax, cetyl alcohol, hydrogenated vegetable oils, microcrystalline waxes, mono- and triglycerides, polyethylene glycol or polyethylene glycol monostearate.
11. (previously presented): The dosage form of claim 9, wherein additional hydrophilic excipient(s) are used, such as alginates, carbopol, gelatin, hydroxypropyl cellulose, hydroxypropyl methylcellulose or methylcellulose.
12. (previously presented): The dosage form of claim 6, wherein an enteric coating layer is applied onto the membrane or matrix system and, optionally, a layer separating the enteric coating from the membrane or matrix system.
13. (previously presented): The dosage form of claim 6, wherein an alkaline-reacting substance is admixed together with the acid-susceptible proton pump inhibitor or the salt thereof.
14. (previously presented): The dosage form of claim 1, wherein said pharmacologically effective amounts are amounts capable to raise gastric pH to above 4 within two hours after administration and to keep it above 4 for at least 4 hours.
15. (original): The dosage form of claim 14, wherein said amounts are capable to keep gastric pH above 4 for at least 8 hours.

16. (previously presented): The dosage form of claim 14, wherein said pharmacologically effective amounts are amounts capable to raise gastric pH to above 3 within 2 hours from administration and to keep it above 3 for at least 4 hours.

17. (original): The dosage form of claim 16, wherein said amounts are amounts capable to keep gastric pH above 3 for at least 8 hours.

18. (previously presented): The dosage form of claim 1, comprising from 100 mg to 1000 mg of antacid agent and/or alginate.

19. (original): The dosage form of claim 18, wherein the antacid agent comprises one or several of aluminum hydroxide, calcium carbonate, magnesium carbonate, basic magnesium carbonate, magnesium hydroxide, magnesium oxide, sodium hydrogen carbonate.

20. (previously presented): The dosage form of claim 1, wherein the acid-susceptible proton pump inhibitor or a salt thereof and excipients, together forming a membrane or matrix system, are present in the form of a multiple-unit system consisting of a plurality of small units, consisting of pellets, granules or beads.

21. (original): The dosage form of claim 20, wherein the small units in the multiple-unit system also contain an outer layer of a H₂ receptor antagonist or a salt thereof.

22. (currently amended): The dosage form of claim 20, wherein the small units are dispersed in a H₂ receptor antagonist or a salt thereof, optionally admixed with pharmaceutically acceptable excipients, ~~such as disintegrant(s).~~

23. (currently amended): The dosage form of claim 1, comprising two halves, one of which comprising an acid-susceptible proton pump inhibitor or a salt thereof in admixture with excipients capable of forming a matrix or membrane system and the other half comprising an H₂ receptor antagonist or a salt thereof, optionally admixed with pharmaceutically acceptable excipients, ~~such as disintegrant(s).~~

24. (currently amended): A capsule dosage form according to claim 1, comprising a capsule.
25. (currently amended): A ~~divided powder/pellet formulation~~ dosage form according to claim 1, comprising a divided powder/pellet formulation.
26. (currently amended): A tablet dosage form according to claim 1, in the form of a tablet.
27. (currently amended): ~~The tablet of~~ A dosage form according to claim 26, ~~being~~ wherein the tablet is divisible.
28. (currently amended): ~~The tablet of~~ A dosage form according to claim 26, ~~being~~ wherein the tablet is dispersible in water.
29. (currently amended): ~~The tablet of~~ A dosage form according to claim 28, ~~comprising~~ wherein the tablet includes a disintegrant.
30. (original): A method for the manufacture of an oral pharmaceutical dosage form comprising pharmacologically effective amounts of an acid-susceptible proton pump inhibitor or a salt thereof and an H2 receptor antagonist or a salt thereof, and at least one pharmaceutically acceptable excipient which results in a delayed release and/or extended release of the acid-susceptible proton pump inhibitor or the salt thereof, and said H2 receptor antagonist or the salt thereof is included in such a way that it is rapidly released from said dosage form, said method comprising forming a first layer comprising said acid-susceptible proton pump inhibitor or salt thereof, and forming a coating thereon of said at least one excipient, and forming a second layer comprising said H2 receptor antagonist or salt thereof surrounding said first layer and said coating, and subsequently formulating the combined product of said first layer, said coating and said second layer into an oral pharmaceutical dosage form.
31. (original): A method according to claim 30, wherein said acid-susceptible proton pump inhibitor is enclosed in said least one excipient, said excipient forming a lipid or water-insoluble matrix.

32. (previously presented): A method according to claim 30, wherein said first layer is formed to pellets, which are subsequently coated with said at least one excipient and are subsequently mixed with a carrier comprising said H2 receptor antagonist or salt thereof.

33. (original): A method according to claim 32, wherein said carrier comprises a pharmacological disintegrant.

34. (previously presented): A method according to claim 30, wherein said combined product is formulated into a tablet.

35. (previously presented): A method according to claim 30, wherein said combined product is formulated into a capsule capable of disintegrating in gastro-intestinal fluids.

36. (previously presented): A method according to claim 30, wherein said oral pharmaceutical dosage form is provided with an enteric coating.

37. (previously presented): A method according to claim 30, wherein said acid-susceptible proton pump inhibitor is selected from the group consisting of lansoprazole, omeprazole, pantoprazole, rabeprazole, pariprazole, lempirazole and their pharmaceutically acceptable salts, enantiomers and salts of enantiomers.

38. (previously presented): A method according to claim 30, wherein said H2 receptor antagonist is selected from the group consisting of cimetidine, ranitidine, nizatidine, famotidine and their pharmaceutically acceptable salts, isomers and salts of isomers.

39. (canceled)

40. (canceled)

41. (previously presented): A method of treating a condition associated with the secretion of gastric acid, wherein an oral pharmaceutical dosage form according to claim 1 is administered in a therapeutically effective amount to an individual human or animal afflicted with said condition.

42. (previously presented): A method for treating an infection by *Helicobacter pylori*, wherein an oral pharmaceutical dosage form according to claim 1 in association with one or more antibiotic agents effective against *H. pylori* is administered in a therapeutically effective amount to an individual or human afflicted with said infection.

43. (canceled)

44. (previously presented): A method according to claim 41, comprising a dose regimen capable of maintaining gastric pH above 4 for at least 95% of a time period starting at 2 hours from the administration of the first dose and extending until 6 hours from the administration of the last dose.

45. (original): A method according to claim 44, wherein said time period is at least one week.

46. (original): A method according to claim 44, wherein said time period is at least two weeks.

47. (original): A method according to claim 44, wherein said time period is at least four weeks.

48. (currently amended): A method according to claim 41, comprising a dose regimen capable of maintaining gastric pH above 3 for at least 95% of a time period starting at 2 hours from the administration of the first dose and extending until 6 hours from the administration of the last dose, in particular for at least four weeks.

49. (new): A method of treating on demand a condition associated with the secretion of gastric acid, wherein an oral pharmaceutical dosage form according to claim 1 is administered in a therapeutically effective amount to an individual human or animal afflicted with said condition.

50. (new): A method of treating a condition associated with the secretion of gastric acid, wherein an oral pharmaceutical dosage form according to claim 1 is administered in a therapeutically effective amount to an individual human or animal afflicted with said condition, wherein the acid-susceptible proton pump inhibitor is selected from lansoprazole, omeprazole,

pantoprazole, rabeprazole, pariprazole, leminoprazole, their pharmaceutically acceptable salts, enantiomers and salts of enantiomers, and the H₂ receptor antagonist is selected from cimetidine, ranitidine, nizatidine and famotidine, their pharmaceutically acceptable salts, isomers and salts of isomers.

51. (new): A method of treating on demand a condition associated with the secretion of gastric acid, wherein an oral pharmaceutical dosage form according to claim 1 is administered in a therapeutically effective amount to an individual human or animal afflicted with said condition, wherein the acid-susceptible proton pump inhibitor is selected from lansoprazole, omeprazole, pantoprazole, rabeprazole, pariprazole, leminoprazole, their pharmaceutically acceptable salts, enantiomers and salts of enantiomers, and the H₂ receptor antagonist is selected from cimetidine, ranitidine, nizatidine and famotidine, their pharmaceutically acceptable salts, isomers and salts of isomers.

52. (new): A method for treating an infection by *Helicobacter pylori*, wherein an oral pharmaceutical dosage form according to claim 1 in association with one or more antibiotic agents effective against *H. pylori* is administered in a therapeutically effective amount to an individual or human afflicted with said infection, wherein the acid-susceptible proton pump inhibitor is selected from lansoprazole, omeprazole, pantoprazole, rabeprazole, pariprazole, leminoprazole, their pharmaceutically acceptable salts, enantiomers and salts of enantiomers, and the H₂ receptor antagonist is selected from cimetidine, ranitidine, nizatidine and famotidine, their pharmaceutically acceptable salts, isomers and salts of isomers.

53. (new): A method according to claim 51, comprising a dose regimen capable of maintaining gastric pH above 4 for at least 95% of a time period starting at 2 hours from the administration of the first dose and extending until 6 hours from the administration of the last dose.

54. (new): A method according to claim 53, wherein said time period is at least one week.

55. (new): A method according to claim 53, wherein said time period is at least two weeks.

56. (new): A method according to claim 53, wherein said time period is at least four weeks.

57. (new): A method according to claim 51, comprising a dose regimen capable of maintaining gastric pH above 3 for at least 95% of a time period starting at 2 hours from the administration of the first dose and extending until 6 hours from the administration of the last dose for at least four weeks.

58. (new): The dosage form of claim 1, wherein the acid-susceptible proton pump inhibitor is selected from lansoprazole, omeprazole, pantoprazole, rabeprazole, pariprazole, leminoprazole, their pharmaceutically acceptable salts, enantiomers and salts of enantiomers, and the H₂ receptor antagonist is selected from cimetidine, ranitidine, nizatidine and famotidine, their pharmaceutically acceptable salts, isomers and salts of isomers.

59. (new): The dosage form of claim 7, wherein an enteric coating layer is applied onto the membrane or matrix system and, optionally, a layer separating the enteric coating from the membrane or matrix system.

60. (new): The dosage form of claim 7, wherein an alkaline-reacting substance is admixed together with the acid-susceptible proton pump inhibitor or the salt thereof.

61. (new): The dosage form of claim 6 or claim 7, wherein an enteric coating layer is applied onto the membrane or matrix system and, optionally, a layer separating the enteric coating from the membrane or matrix system, the acid-susceptible proton pump inhibitor is selected from lansoprazole, omeprazole, pantoprazole, rabeprazole, pariprazole, leminoprazole, their pharmaceutically acceptable salts, enantiomers and salts of enantiomers, and the H₂ receptor antagonist is selected from cimetidine, ranitidine, nizatidine and famotidine, their pharmaceutically acceptable salts, isomers and salts of isomers.

62. (new): The dosage form of claim 20, wherein the small units are dispersed in a H₂ receptor antagonist or a salt thereof, optionally admixed with pharmaceutically acceptable excipients that comprise disintegrant(s).

63. (new): The dosage form of claim 20, wherein the small units are dispersed in a H₂ receptor antagonist or a salt thereof, optionally admixed with pharmaceutically acceptable excipients, and which dosage form is in the form of a capsule.
64. (new): The dosage form of claim 63, wherein the pharmaceutically acceptable excipients comprise disintegrant(s).
65. (new): The dosage form of claim 20, wherein the small units are dispersed in a H₂ receptor antagonist or a salt thereof, optionally admixed with pharmaceutically acceptable excipients, which dosage form is in the form of a capsule, the acid-susceptible proton pump inhibitor is selected from lansoprazole, omeprazole, pantoprazole, rabeprazole, pariprazole, leminoprazole, their pharmaceutically acceptable salts, enantiomers and salts of enantiomers, and the H₂ receptor antagonist is selected from cimetidine, ranitidine, nizatidine and famotidine, their pharmaceutically acceptable salts, isomers and salts of isomers.
66. (new): The dosage form of claim 65, wherein the pharmaceutically acceptable excipients comprise disintegrant(s).
67. (new): The dosage form of claim 1, comprising two halves, one of which comprising an acid-susceptible proton pump inhibitor or a salt thereof in admixture with excipients capable of forming a matrix or membrane system and the other half comprising an H₂ receptor antagonist or a salt thereof, optionally admixed with pharmaceutically acceptable excipients that comprise disintegrant(s).
68. (new): The dosage form of claim 1, comprising from 100 mg to 1000 mg of antacid agent and/or alginate, and wherein the acid-susceptible proton pump inhibitor is selected from lansoprazole, omeprazole, pantoprazole, rabeprazole, pariprazole, leminoprazole, their pharmaceutically acceptable salts, enantiomers and salts of enantiomers, and the H₂ receptor antagonist is selected from cimetidine, ranitidine, nizatidine and famotidine, their pharmaceutically acceptable salts, isomers and salts of isomers.

69. (new): A method for the treatment of a condition associated with the secretion of gastric acid, wherein two separate oral dosage forms are administered concomitantly, one dosage form comprising a pharmacologically effective amount of an acid-susceptible proton pump inhibitor or a salt thereof and at least one pharmaceutically acceptable excipient(s) which results in a delayed release and/or extended release of the acid-susceptible proton pump inhibitor or the salt thereof, and the other comprising a pharmacologically effective amount of an H2 receptor antagonist or a salt thereof, said H2 receptor antagonist or the salt thereof being included in such a way that it is rapidly released from said dosage form.

70. (new): A method according to claim 69, wherein the acid-susceptible proton pump inhibitor is selected from lansoprazole, omeprazole, pantoprazole, rabeprazole, pariprazole, leminoprazole, their pharmaceutically acceptable salts, enantiomers and salts of enantiomers, and the H2 receptor antagonist is selected from cimetidine, ranitidine, nizatidine and famotidine, their pharmaceutically acceptable salts, isomers and salts of isomers.

71. (new): A method for treating an infection by *Helicobacter pylori*, wherein two separate oral dosage forms are administered concomitantly together with one or more antibiotic agents effective against *Helicobacter pylori*, one oral dosage form comprising a pharmacologically effective amount of an acid-susceptible proton pump inhibitor or a salt thereof and at least one pharmaceutically acceptable excipient(s) which results in a delayed release and/or extended release of the acid-susceptible proton pump inhibitor or the salt thereof, and the other comprising a pharmacologically effective amount of an H2 receptor antagonist or a salt thereof, said H2 receptor antagonist or the salt thereof being included in such a way that it is rapidly released from said dosage form.

72. (new): A method according to claim 71, wherein the acid-susceptible proton pump inhibitor is selected from lansoprazole, omeprazole, pantoprazole, rabeprazole, pariprazole, leminoprazole, their pharmaceutically acceptable salts, enantiomers and salts of enantiomers, and the H2 receptor antagonist is selected from cimetidine, ranitidine, nizatidine and famotidine, their pharmaceutically acceptable salts, isomers and salts of isomers.

73. (new): A dosage form according to claim 1 wherein the pharmaceutically acceptable excipient(s) results in an extended release of the acid-susceptible proton pump inhibitor or the salt thereof.

74. (new): A dosage form according to claim 1 wherein the pharmaceutically acceptable excipient(s) results in a delayed (until the large intestine is reached) release and/or extended release of the acid-susceptible proton pump inhibitor or the salt thereof.

75. (new): A dosage form according to claim 1 wherein the pharmaceutically acceptable excipient(s) results in a delayed release and extended release of the acid-susceptible proton pump inhibitor or the salt thereof.

76. (new): A dosage form according to claim 1 wherein the pharmaceutically acceptable excipient(s) results in a delayed (until the large intestine is reached) release and extended release of the acid-susceptible proton pump inhibitor or the salt thereof.

77. (new): A method of treating a condition associated with the secretion of gastric acid, wherein an oral pharmaceutical dosage form according to any one of claims 73 to 76 is administered in a therapeutically effective amount to an individual human or animal afflicted with said condition.

78. (new): A method for treating an infection by *Helicobacter pylori*, wherein an oral pharmaceutical dosage form according to any one of claims 73 to 76 in association with one or more antibiotic agents effective against *H. pylori* is administered in a therapeutically effective amount to an individual or human afflicted with said infection.

79. (new): A method according to claim 69, wherein the pharmaceutically acceptable excipient(s) results in an extended release of the acid-susceptible proton pump inhibitor or the salt thereof.

80. (new): A method according to claim 71, wherein the pharmaceutically acceptable excipient(s) results in an extended release of the acid-susceptible proton pump inhibitor or the salt thereof.

81. (new): A method according to claim 69, wherein the pharmaceutically acceptable excipient(s) results in a delayed (until the large intestine is reached) release and/or extended release of the acid-susceptible proton pump inhibitor or the salt thereof.

82. (new): A method according to claim 71, wherein the pharmaceutically acceptable excipient(s) results in a delayed (until the large intestine is reached) release and/or extended release of the acid-susceptible proton pump inhibitor or the salt thereof.

83. (new): A method according to claim 69, wherein the pharmaceutically acceptable excipient(s) results in a delayed release and extended release of the acid-susceptible proton pump inhibitor or the salt thereof.

84. (new): A method according to claim 71, wherein the pharmaceutically acceptable excipient(s) results in a delayed release and extended release of the acid-susceptible proton pump inhibitor or the salt thereof.

85. (new): A method according to claim 69, wherein the pharmaceutically acceptable excipient(s) results in a delayed (until the large intestine is reached) release and extended release of the acid-susceptible proton pump inhibitor or the salt thereof.

86. (new): A method according to claim 71, wherein the pharmaceutically acceptable excipient(s) results in a delayed (until the large intestine is reached) release and extended release of the acid-susceptible proton pump inhibitor or the salt thereof.